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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/566,188	06/15/2007	Robert D. Hargens	RE/3-33299A	2101

74550 7590 05/26/2010

Novartis Consumer Health, Inc.
OTC Patent Group
200 Kimball Drive
Parsippany, NJ 07054-0622

EXAMINER	
VALDEZ, DEVE E	

ART UNIT	PAPER NUMBER
1796	

NOTIFICATION DATE	DELIVERY MODE
05/26/2010	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

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patent.office@novartis.com
maria.stachura@novartis.com

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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Application Number: 10/566,188
Filing Date: June 15, 2007
Appellant(s): HARGENS ET AL.

Frank A. Smith
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed March 2, 2010 appealing from the Office action mailed January 5, 2010.

(1) Real Party in Interest

The examiner has no comment on the statement, or lack of statement, identifying by name the real party in interest in the brief.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The following is a list of claims that are rejected and pending in the application:

1-8

(4) Status of Amendments After Final

The examiner has no comment on the appellant's statement of the status of amendments after final rejection contained in the brief.

(5) Summary of Claimed Subject Matter

The examiner has no comment on the summary of claimed subject matter contained in the brief.

(6) Grounds of Rejection to be Reviewed on Appeal

The examiner has no comment on the appellant's statement of the grounds of rejection to be reviewed on appeal. Every ground of rejection set forth in the Office action from which the appeal is taken (as modified by any advisory actions) is being maintained by the examiner except for the grounds of rejection (if any) listed under the subheading "WITHDRAWN

REJECTIONS." New grounds of rejection (if any) are provided under the subheading "NEW GROUNDS OF REJECTION."

(7) Claims Appendix

The examiner has no comment on the copy of the appealed claims contained in the Appendix to the appellant's brief.

(8) Evidence Relied Upon

EP 1175915 A1	**Hughes et al.**	**1-2002**
US 7067116 B1	**Bess et al.**	**6-2006**
WO 01/70194	**Bess et al.**	**9-2001**

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Rejection I: Rejection of claims 1 and 2 under 35 U.S.C 102(b)

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1 and 2 are rejected under 35 U.S.C. 102(b) as being anticipated by EP 1175915 (hereinafter '915).

Regarding claim 1, '915 teaches a method for the aqueous loading of water soluble and soluble pharmaceutically active substances onto ion exchange resins [0001]. The complex formed between a polymeric material and an active substance can be used in taste masking of

bitter drugs, control of the site of administration of drugs, control of the release of flavor substances, and stabilization of unstable substances [0002]. The method for loading active substances into an ion exchange resin is to dissolve an acidic or basic, ionizable active substance in water, and then mix it with a suitable ion exchange resin. Also, '915 teaches a method for preparing a resinate comprising blending a poorly water soluble or soluble active substance with an ion exchange resin and a solvent selected from the group consisting water, a water miscible solvent, a water-immiscible solvent or mixtures thereof to form an active substance/resin/solvent mixture [0020]. The water immiscible solvents used in the invention are hydrocarbons, halogenated hydrocarbons, ethers, ketones, and esters [0041] which are considered to be non-polar solvents. Furthermore, the claimed washing step of the loaded matrix with a non polar solvent is considered to be met by EP 1175915 wherein it is taught in paragraph [0051] that the water-immiscible solvent can be removed from the final mixture by filtration [0051] and within Example 1 paragraph [0054] wherein after addition of water (it is noted that the water performs the function of the aforementioned water and solvent in paragraph [0020]) and shaking the water is drained from the mixture and within Examples 3-5 in paragraph [0057-0059] wherein the loaded resin is contacted with a non-polar solvent.

Regarding claim 2, '915 teaches AMBERLITE IRA67 which is a polymeric matrix that has a weak acidic cation exchange resins having carboxylic acid functional groups (Examples 1 and 2).

Rejection II: Rejection of claims 3-8 under 35 U.S.C 103(a)

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 3-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over EP 1175915 (hereinafter '915) in view of WO 01/70194 (hereinafter '194).

To further advance the prosecution of this invention, BESS et al. (U.S. Patent No. 7,067,116, hereinafter BESS), which is an English Equivalent of WO 01/70194 will be used in this rejection.

Regarding claims 3-8, '915 teaches a method for the aqueous loading of water soluble and soluble pharmaceutically active substances onto ion exchange resins [0001]. The complex formed between a polymeric material and an active substance can be used in taste masking of bitter drugs, control of the site of administration of drugs, control of the release of flavor substances, and stabilization of unstable substances [0002]. The method for loading active substances into an ion exchange resin is to dissolve an acidic or basic, ionizable active substance in water, and then mix it with a suitable ion exchange resin. Also, '915 teaches a method for preparing a resinate comprising blending a poorly water soluble or soluble active substance with an ion exchange resin and a solvent selected from the group consisting water, a water miscible solvent, a water-immiscible solvent or mixtures thereof to form an active substance/resin/solvent mixture [0020]. The water immiscible solvents used in the invention are hydrocarbons, halogenated hydrocarbons, ethers, ketones, and esters [0041] which are considered to be non-polar solvents. Furthermore, the claimed washing step of the loaded matrix with a non polar

solvent is considered to be met by EP 1175915 wherein it is taught in paragraph [0051] that the water-immiscible solvent can be removed from the final mixture by filtration [0051] and within Example 1 paragraph [0054] wherein after addition of water (it is noted that the water performs the function of the aforementioned water and solvent in paragraph [0020]) and shaking the water is drained from the mixture and within Examples 3-5 in paragraph [0057-0059] wherein the loaded resin is contacted with a non-polar solvent.

However, while '915 teaches the use of hydrocarbons, '915 does not teach a hexane, heptane, octane, isooctane, cyclopentane, cyclohexane, methyl cyclohexane, ethyl cyclohexane, carbon disulfide, trichloroethylene, carbon tetrachloride, benzene , toluene, xylene, propenol, butanol, butanone, and mixtures thereof used for washing the loaded matrix having a polarity of less than 5, 3, and 1.

In the same field of endeavor of masking the taste of pharmaceutically active agent, BESS teaches fast dissolving orally consumable films containing an agent to mask the taste of a pharmaceutically active agent which is dextromethorphan hydrobromide and diphenydramine hydrochloride (Table A) to such as films containing an ion exchange resin as the taste masking agent. The taste-masking agent is an AMBERLITE IRP-69 resin (Col. 4, lines 43-44) and EUDRAGIT S can also be used a taste masked polymer which are coated with solvents such as hexane and toluene (Col. 11, lines 28-30). Even though BESS does not teach hexane as a nonpolar solvent used for washing the loaded matrix as a use in his composition, the reference does disclose the use of the claimed hydrocarbon to produce an analogous composition therefore, it would have been obvious to use hexane as the disclosed hydrocarbon of the primary reference.

Regarding claims 7-8, '915 teaches anionic exchange resins and cationic exchanges resins such as AMBERLITE IRA67 [0021, Examples 1 and 2]. However, '915 does not teach the polymeric matrix having anionic functional groups used is a hydrogen form cation and the active-loaded hydrogen from cation exchange resin obtained is further neutralized with a metal ion.

In the same field of endeavor of taste masking a pharmaceutically active agent, BESS teaches AMBERLITE IRP-69 (Col. 4, lines 60-62) which is a polymeric matrix that has strong acidic cation exchange resin having sulfonic acid functional groups and is neutralized by sodium ions.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to utilize AMBERLITE IRP-69 of BESS for the benefit of taste-masking pharmaceutically active agents such as dextromethorphan hydrobromide.

(10) Response to Argument

Response to Arguments Regarding Rejection 1

Appellant has argued that there is no washing step in EP 1175915. In response, it is noted that appellant's claimed washing step is not limited with respect to what is being removed or what purity is to be obtained, therefore, the position is taken that the contacting of the loaded resin with solvent as disclosed within the reference is adequate to meet the "washing" step to the extent claimed. Appellant has argued that the claimed non-polar solvent must not be another solution of the active, however, this argument is not commensurate in scope with the claim because the claim places no such limitation on what components are to be used to perform the washing step. Appellant's argument that the washing step is the step subsequent to loading to

remove unbound active has been considered, however, there is no evidence on the record that the disclosed contacting of solvent with the loaded resin would not also remove unbound active.

Response to Arguments Regarding Rejection 2

Appellant's response with respect to rejection 2 is based on the primary reference lacking any suggestion of appellant's claimed washing step. In response this issue has been addressed above with the respect to arguments concerning rejection 1. The examiner has set forth previously how the primary reference is considered to disclose a washing step to the extent claimed.

(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

/Rabon Sergent/

Primary Examiner, Art Unit 1796

Conferees:

James J. Seidleck / JJS/

Supervisory Patent Examiner, Art Unit 1796

David Wu / DW/

Supervisory Patent Examiner, Art Unit 1796

/dv/ 5/20/10